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JUN 20 2007

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re United States Patent Application of:)	Docket No.:	4179-126
)		
Applicants: SHAH, Tilak M.)	Conf. No.:	2458
)		
Application No.: 10/633,238)	Art Unit:	3728
)		
Date Filed: August 1, 2003)	Examiner:	David Fidei
)		
Title: PRESS-FLAT CENTRIFUGE TUBE AND SPECIMEN COLLECTION ASSEMBLY COMPRISING SAME)	Customer No.:	23448
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DECLARATION OF TILAK M. SHAH UNDER 37 CFR 1.132 IN
U.S. PATENT APPLICATION NO. 10/633,238

1. My name is Tilak M. Shah. I have Bachelor of Science degrees in Chemistry and Physics from Bombay University, and Master's degree in Chemistry from the City College of New York. I have over twenty-five years of experience working with polyurethane, elastomers, and other polymers in various research, product development, and marketing roles for various corporations, including the Upjohn Company, Dow Chemical USA, Pacrim International, Inc., TS Polymers, Inc., Polygenex International, Inc., and Polyzen, Inc. I have been a member of the American Chemical Society and the Society of Plastics Engineers since 1972. In recent years, my expertise has been focused on the medical device industry. I have served as the President and CEO of Polyzen, Incorporated since 1997. Polyzen's primary business area include: (1) polymer formulation and compounding; and (2) development and assembly of medical devices, including medical balloons, stents, probes, organ bags, protective sleeves, specialty tubing, and containers.

2. I have authored and co-authored a large number of technical papers and publications relating to polymers and elastomers, including: Thermoplastics Polyamide section in *Modern Plastics Encyclopedia*, 1985-1986; "Polyamide Elastomer" chapter in handbook of "Thermoplastics Elastomer," 1988; Radiopaque Polymer Formulation for Medical Devices, *Medical Device & Diagnostic Industry*, March 2000; Polyurethane Thin Film Welding for Medical Device Application, *Medical Device & Diagnostic Industry*, September 2002; Maximizing Tubing Functionality, Part I and Part II, *Medical Device & Diagnostic Industry*, October and November 2003; and Improved Process for Bonding Polymeric Thin Film to Textiles for Healthcare and other Applications, *Paper presented at Clemson University Medical Textile Conference*, March 2004.

3. I am named as an inventor or co-inventor on a large number of U.S. patents, foreign patents, and pending patent applications relating to polymers, polymeric articles, and methods for fabricating and using polymeric articles, including, for example, U.S. Patent Nos. 7,112,186; 6,805,662; 6,712,832; 6,663,646; 6,509,094; 6,492,012; 6,460,541; 6,352,077; 6,291,543; 6,258,869; 5,833,915; 5,799,333; 5,679,423; 5,644,798; 5,571,567; 5,554,673; 5,469,863; 5,245,195; 4,950,239; RE31,671; 4,202,957; 4,000,117; and 3,951,657. I am the inventor of the subject matter of the subject patent application.

4. By virtue of my education and work experience, I am highly familiar with methods for forming polymeric tubes and similar containers.

5. The claims of the instant U.S. Patent Application No. 10/633,238 are directed to a centrifuge tube having integral hinge elements at opposing sides of the body thereof to facilitate compressive flattening of at least a portion of the body, either with the body having a substantially uniform diameter along an open proximal end (e.g., claim 22) or with the proximal end having a cross-sectional area at least as large as an average cross-sectional area of the body (e.g., claim 31).

6. I understand that all of the claims of the instant patent application have been rejected. I have reviewed the present application and the substance of the Office Action dated February 20, 2007 in the present application. Based on my review of these documents, I have the following comments relating to the February 20, 2007 Office Action.

7. In the February 20, 2007 Office Action, the Examiner states that:

...it is not agreed [that] one skilled in the art would have gleaned the open proximal end 20 is to have a cross-sectional area at least as large as the average cross sectional area of the centrifuge tube.

I disagree with the Examiner's conclusion in multiple respects.

8. The present application includes twelve Figures. FIGS. 1-7 show alternating views of centrifuge tubes having integral hinge elements. In FIGS. 1, 3, 5, and 6, the hinge elements are illustrated as aligned parallel with the drawing page, whereas in FIGS. 2, 4, and 7, the hinge elements are illustrated as perpendicular to the drawing page. In each instance, the open proximal end portion (e.g., portions 20, 104 defining opening 18) is illustrated as being at least as large or larger in outer diameter as the body of the associated tube 10, 100 – and each tube has a reduced diameter portion along depressions 26, 112, 118.

9. The present application refers to teach centrifuge tube as having a singular wall thickness. See, for example, page 11, first paragraph, (referring to “[t]he wall thickness of the centrifuge tube” and indicating that “[t]he centrifuge tube may have a wall thickness that is greater than 5 mils (.005 inch) in thickness ...”) Nothing in the instant application suggests, to one of ordinary skill in the art at the time the present invention was made, any variation in wall thickness of the proximal end portion relative to the remainder of the body of the centrifuge tube.

10. The present application indicates that the centrifuge tubes of the invention are fabricated by “extrusion blow molding or rotational molding.” Application, page 4, fourth paragraph and page 11, first paragraph. Reasonably accurate descriptions of these processes are available online, for example, at http://en.wikipedia.org/wiki/Blow_molding and http://en.wikipedia.org/wiki/Rotational_molding. Both extrusion blow molding and rotational molding are widely recognized, by those of ordinary skill in the art at the time the present invention was made, to produce articles having reasonably uniform wall thickness.

11. Upon review of the drawings showing an open proximal end portion having an outer diameter at least as large or larger as that of the body of the associated tube, together with the disclosure suggesting a singular centrifuge tube wall and the fact that such centrifuge tubes are to be made by molding processes that inherently produce reasonably consistent wall thicknesses, one of ordinary skill in the art at the time the present invention was made would readily understand that the application as originally filed discloses “an open proximal end [having] a cross-sectional area at least as large as the average cross-sectional area [of the centrifuge tube body]” as recited in certain claims pending in the present application.

12. Centrifuge tubes are commonly understood to be substantially cylindrical in shape, occasionally with a conical well or other narrowed tip, for example to aid in precipitate compaction. Many, if not most, centrifuge tubes typically have a diameter of about one inch or

less to permit their use with widely available centrifuges of conventional size, and to avoid the need for excessive amounts of wash or elution liquid. I am not aware of any commercially available centrifuge tube that does NOT have an open proximal end with a cross-sectional area that is at least as large as an average area of the tube body.

13. The requirement of claim 22 that the body have "a substantially uniform diameter along the open proximal end" permits the open proximal end of the claimed centrifuge tube to be sufficiently large to receive a specimen-containing swab element without requiring an unnecessarily large and unwieldy tube that may not be suitable for convenient for centrifugation.

14. The requirement of claim 31 that "the open cross-sectional end [have] a cross sectional area at least as large as the average cross-sectional area" ensures that the open proximal end is sufficiently large to receive a specimen-containing swab element without requiring an unnecessarily large and unwieldy tube that may not be convenient for centrifugation, while recognizing that the body may have a non-uniform cross-sectional area along its length.

I declare under penalty of perjury that the facts set forth in this declaration are true and correct, that all statements made of my own knowledge are true, and that all statements made on information and belief are believed to be true. I have been hereby warned that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001, and that such willful false statements may jeopardize the validity of the application or any resulting registration.

Executed at Alex, North Carolina, this 20th day of June 2007.

Tilak M. Shah
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